REMARKS

In view of the above amendments, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 1-6 and 20-24 under 35 U.S.C. §101 for lack of utility is respectfully traversed.

The claims of the above-identified patent application have a specific, substantial and credible asserted utility. As described in the specification as filed the proteins of the present invention have transcriptional regulatory activity (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.) . It is the position of the U.S. Patent and Trademark Office ("PTO") that the application has only provided guesses as to the utility. Applicant's respectfully disagree. As explicitly stated on page 15, lines 17-18, "[t]he proteins have transcriptional activation activity".

Accordingly, the specification identifies an asserted utility. Therefore, the PTO must determine if the asserted utility is specific, substantial and credible. (Manual of Patent Examining Procedure ("MPEP") 2107(B)). Only one credible asserted utility is needed to meet the criteria for 35 USC § 101 (MPEP 2107(B)(1)(ii)). Further, an applicant's asserted utility creates a presumption of utility that is sufficient to satisfy the utility requirement of 35 USC § 101 (MPEP 2107.02 III). If the asserted utility is credible, a rejection based of lack of utility is not appropriate (Id.). In fact, "Office personnel should not begin an evaluation of utility by assuming that an asserted utility is likely to be false, based on the technical field of the invention or for other general reasons."(MPEP 2107.02 III.A.)

In particular, the application as filed describes the transcriptional regulatory activity of the protein (pg. 29, lines 25-30, pg. 15, lines 17-18, pg. 41, line 29-pg. 43, line 32.) As shown in the example, the *GAL4-TIG-1* expression plasmid showed a

threefold increase in CAT expression when compared to CAT activity of the GAL4 DNA binding domain (pg. 42, lines 11-30). Further, TPA induced K562 cells cotransfected with the *CAT* reporter construct and the GAL4-TIG-1 expression vector increase CAT expression by 11-14 fold as compared to uninduced cells (pg. 43, lines 1-12; Figure 7C).

In addition, the structure of the protein of the present invention is similar to a co-activator complex that mediates chromatin-directed transcriptional activation (pg. 44, lines 3-13). It is the PTO's position that structural similarity to a known protein does not suggest functional similarity. Applicants disagree. As stated in MPEP 2107.03 II, evidence of structural similarity can be considered in an evaluation of utiltiy. "Such evidence should be given appropriate weight in determining whether one skilled in the art would find the asserted utility credible." (Id.)

Accordingly, because there is no reason to doubt the assertion that the proteins of the present invention have transcriptional regulatory activity and that such proteins have a well-established utility, applicants asserted utility for the present case is sufficient to meet the utility requirement of 35 USC § 101. No further experimentation is necessary to attribute a utility to the claimed proteins. See *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (1966). Accordingly, the rejection of claims 1-17, 23 and 24 for lack of utility is improper and should be withdrawn.

In view of the foregoing, Applicants submit that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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